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Lidia Pino
19 Swarthmore Lane
Dix Hills, NY 11746

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Joseph Levitt, Director for Food and Safety and Applied Nutrition
FDA 200 C Street SW
Washington, D.C. 20204

June 17, 1999

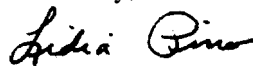
Dear Mr. Levitt:

I have a three-year-old son with a life threatening food allergy. The only way to keep him safe is complete avoidance of peanuts and peanut products. I have become a constant label reader, as well as educator to many on this serious subject.

The reason for this letter is to see how we can get manufacturers to list "all" ingredients very specifically on the labels. It is currently acceptable to use the term "natural flavoring" without noting exactly what flavoring is used. Manufacturers may also use "vegetable oil" without labeling the type of oil that is being used. Because peanut is a natural flavoring I have a valid concern each time I run across a label with that term used. When this is listed on a product I would like my son to use, I must contact the manufacturer to find out, specifically, what flavoring is used. I must do this when "vegetable oil" is on a label as well. This is a very time consuming, tedious task. If the manufacturer was required to list these items, it would help our plight tremendously.

Please remember this issue in **future** meetings, regarding labeling. Thank you for your time and consideration in this matter.

Sincerely,



Lidia Pino

99P-2148

CH

AUG 31 1999

Ms. Lidia Pino
19 Swarthmore Lane
Dix Hills, NY 11746

Dear Ms. Pino:

This is in response to your letter of June 17, 1999, to Joseph Levitt, Director, Center for Food Safety and Applied Nutrition, regarding the labeling of all ingredients that are used in the preparation of foods.

We understand your concern regarding your son's allergy to peanuts. FDA, as well, is concerned about informing consumers about allergenic substances in food.

Let me begin by explaining that the Food, Drug, and Cosmetic Act (the act) requires, in virtually all cases, that labels of food fabricated from two or more ingredients bear a declaration of each ingredient, by its common or usual name, in descending order of predominance by weight in the ingredient statement. There are two very narrow exemptions from these ingredient labeling requirements. First, section 403(i) of the act provides that spices, flavorings, and colorings may be declared collectively without naming each one. Secondly, FDA regulations (**21 CFR 101.100(a)(3)**) exempt, from ingredient declaration, incidental additives such as processing aids, that are present in a food at insignificant levels and that do not have a technical or functional effect in the finished food. In other words, when an ingredient is used during processing or is added as a secondary ingredient, and is present at insignificant levels and has no **technical** or functional effect in the finished food, the ingredient may not be required to be declared in ingredient labeling.

Regarding the use of the term "vegetable oil," Part **101.4(b)(14)** of the Code of Federal Regulations (copy enclosed) states that each oil ingredient of a food intended for human consumption must be declared by its common or usual name (e.g., "cottonseed oil") in its order of predominance by weight. Blends of fats and/or oils must be listed in their order of predominance in the foods as "____ shortening" or "blend of ____ oils," the blank to be filled in with the word "vegetable," "animal," or "marine," whichever is applicable, followed by the common or usual name of

each fat or oil in parentheses, e.g., "vegetable oil shortening (soybean and cottonseed oil)." Thus, FDA requires manufacturers to list all the specific types of oils included in the food when the term "vegetable oil" is used.

As stated above, FDA recognizes that some foods are a concern to allergic consumers and is considering whether it is necessary to clarify or amend its ingredient labeling regulations to ensure that manufacturers fully understand the circumstances in which allergenic food ingredients must be declared. The agency addressed its concerns about declaration of allergenic substances in food in a 1996 Notice to Manufacturers (copy enclosed). Because we had received reports of adverse reactions to foods in which allergenic substances were likely used as flavors, and not declared by name, FDA discussed in the notice whether an allergenic ingredient in a spice, flavor, or color should be required to be declared, section 403(i) not withstanding. On a substance-by-substance basis, the agency has required ingredients covered by the exemption in section 403(i) to be declared when necessary to protect individuals who experience adverse reactions to the substance. The agency also discussed, in the notice, its concern with the inadvertent introduction of an allergenic ingredient to a food. For example, a bakery that is manufacturing two food products on one production line, one product with peanuts and one without, may inadvertently introduce traces of peanuts or peanut products into the product that does not normally contains peanuts. Good manufacturing practices not withstanding, the agency is considering how best to alert sensitive consumers to the inadvertent introduction of allergens into food since its presence would not be declared in the ingredient statement.

The agency is aware that some manufacturers are voluntarily labeling their products with statements such as "may contain (insert the name of allergenic ingredient)." FDA has advised manufacturers that, because adhering to good manufacturing practice (GMP) is essential for effective reduction of adverse reactions, such precautionary labeling should not be used in lieu of adherence to GMP. The agency has urged manufacturers to take all steps necessary to eliminate cross contamination and to ensure the absence of the allergenic food before relying on "may contain" labeling to protect the consumer.

We have recently received a citizen petition (docket number 99P-2148/CP) raising concerns similar to those raised in your letter

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and requesting FDA to amend its food labeling regulations to require the specific ingredient listing of spices and natural and artificial flavors on the label. We will forward your letter to the Dockets Management Branch to be included with other letters responding to the petition. Please be assured that we **will** consider all comments before making a final decision **on** this issue.

If you have any further questions on this issue, do not hesitate to contact us.

Sincerely yours,

Catalina Ferre-Hockensmith
Division of Programs
and Enforcement Policy
Office of Food Labeling
Center for Food Safety
and Applied Nutrition

Enclosure(s) : CFR Part 101.4(b)(14)
1996 Notice to Manufacturers

cc: HFS-150 (r/f, project 65829)

HFS-155

HFS-158 (r/f, Hockensmith w/cpy incoming)

HFS-636 (w/cpy incoming)

R/D:HFS-158:CFERRE-HOCKENSMITH:8/4/99:C:\GLUTEN\PINO.GLU

Revised:HFS-158:CFERRE-HOCKENSMITH:8/9/99 PER FSATCHELL comments

Init:HFS-158:FSATCHELL:8/11/99

F/T:sdl:8/12/99